

**SUMMARY OF THE
ON-SITE ASSESSMENT COMMITTEE MEETING
NOVEMBER 22, 1999**

The On-site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on Monday, November 22, 1999, at 10:30 a.m. Eastern Standard Time (EST). In the absence of the committee's chair, the meeting was jointly administered by the committee members in attendance. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The primary purpose of the meeting was to discuss committee comments on basic assessor training materials prepared for the United States Environmental Protection Agency (USEPA) by a private contractor.*

INTRODUCTION

Dr. Margot Hunt, USEPA, joined the committee to discuss comments on draft training materials she had distributed electronically prior to the meeting. Several participants referenced an e-mail forwarded to committee members by Steve Baker concerning On-site Assessment Committee review of the training proposal from the Global Institute of Environmental Scientists (GIES). It was agreed that the committee should spend its time on the training course rather than on the GIES proposal. Dr. Hunt reminded committee members that they needed to finish their review of the training materials during this meeting so that she could authorize the contractor to make changes to the materials before December 31, 1999.

TRAINING ISSUES

It was noted that Unit Two of the Basic NELAC Assessor Training Course ("NELAC Overview") will state that "the Accrediting Authority Review Board (AARB) has the responsibility to monitor EPA to assure that EPA is following the NELAC standards...." A participant took issue with this statement and commented that the AARB has the responsibility to monitor NELAP rather than EPA. In response, other participants noted that the statement is consistent with the NELAC Program Policy and Structure Standard (Section 1.6.3) and that the NELAC Standards must be reviewed in accordance with the NELAC process. The issue was deemed one that should be discussed further at the upcoming interim meeting.

Dr. Hunt then led the committee item-by-item through the list of comments she had received on Units 3-17 of the Basic NELAC Assessor Training Course. The committee made the general observation that areas of the training materials were not consistent with the language of the applicable NELAC Standard. It was decided that committee members would send those inconsistencies, along with the appropriate Standard references, electronically to Dr. Hunt.

The committee raised the following major issues in discussion of each unit:

Unit 3 ("Requirements of Accrediting Authority and Accreditation of Laboratories") - It was noted that an assessor does not have to be an expert on EPA regulations and, therefore, should not be required to assess whether a laboratory is in compliance with EPA programs. For

this reason, it was suggested that training materials be clarified to state that the laboratory must show it is in compliance with *relevant laboratory requirements under each EPA program*.

It was noted that Unit 3 should be reviewed to make sure that it is consistent with the NELAC On-site Assessment Standard and that the NELAC Standards themselves should be reviewed to make sure that the On-site Assessment Standard (Sections 3.5.3 and 3.6.4) is consistent with the Quality Systems Standard.

Unit 4 (“Proficiency Testing”) - There were no comments on suggested changes to Unit 4.

Unit 5 (“Standards of Ethical Conduct”) - It was noted that the NELAC On-site Assessment Standard (Section 3.2.2) stipulates that an assessor should sign a waiver to certify that no conflict of interest exists. The committee then entered into a discussion of Confidential Business Information (CBI) issues. A participant noted that the question of whether a third party assessor may sign CBI papers on behalf of the Accrediting Authority is not explicitly addressed in the Standard. It was also noted that government employees have accountability regarding CBI and that non-government assessors should be required to sign a confidentiality agreement that holds them to the same accountability as government employees. Although client information is not considered CBI under federal law, participants noted that the confidentiality agreement should also cover such information. It was generally agreed that this issue requires some form of clarification comment. The issue was tabled for discussion at the next interim meeting in order to get input from NELAC stakeholders.

Unit 6 (“Overview of Laboratory Assessment”) - It was suggested that the training materials include “real-world” examples of extraneous information inappropriate to the assessor’s logbook. Such examples might include notes to themselves, telephone numbers, and inflammatory or accusatory language.

Unit 7 (“Pre-Assessment”) - It was noted that this training unit refers to an “assessment plan” and that the On-site Assessment Standard refers to “assessment planning.” It was suggested that the wording be changed to “assessment planning” and that examples of a formal Assessment Plan document be added later. A participant noted that developing an Assessment Plan would be a good exercise for the pilot training course.

Unit 8 (“Interviewing Techniques”) - This unit had already been discussed by the committee.

Unit 9 (“Assessment”) - This unit had already been discussed by the committee.

Unit 10 (“Post-Assessment”) - There were no comments on suggested changes to Unit 10.

Unit 11 (“Quality Systems Overview”) - The committee noted that this unit should reference “elements” of the Quality System rather than “categories.”

Unit 12 (“Quality Systems #1”) - The committee noted that specific examples for use in assessor training will accumulate as NELAC assessments are being performed. A participant suggested that any committee members attending the pilot course note topics for which examples

would be helpful in the future. It was suggested that the training materials needed clarification as to a “legally identifiable” laboratory and that references to how many laboratory staff members report to one person be dropped. It was further suggested that the NELAC On-site Assessment Committee coordinate more formally with the NELAC Quality Systems Committee on issues that bridge the two committees.

Unit 13 (“Quality Systems #2”) - The committee made the general comment that it should be verified that the Quality Systems units are consistent with the NELAC Quality Systems Standard. It was noted that the Standard (Section 5.14.a) stipulates that, “The laboratory shall advise in writing of its intention to sub-contract any portion of its testing to another party.” The committee recommended that the contractor add the phrase “in writing” to this unit and also noted that the advisement may be made by fax or e-mail.

Unit 14 (“Overview of NELAC Laboratory Assessment”) - There were no comments on suggested changes to Unit 14.

Unit 15 (“NELAC Pre-Assessment”) - It was noted that the NELAC On-site Assessment Standard (Section 3.2.3) contains a five-day course outline in which Day One covers basic auditing techniques and skills, but not how to conduct a pre-assessment. The outline’s Day Four covers how to conduct an on-site assessment. A participant asked if anyone had gone through the draft training materials to see how many hours are being spent on Quality Systems. Dr. Hunt replied that this had not yet been done. The participant also suggested combining Units 7 (“Pre-Assessment”) and 15 (“NELAC Pre-Assessment”). The committee made the general comment that much of the training course materials seemed to be redundant in regard to how to perform an assessment and lacking in time spent on the NELAC Standards. The committee engaged in considerable discussion of document review. Several participants favored an assessor taking the approach of asking a laboratory for a document index and using that index to request specific documents for review. Other participants favored an assessor reviewing all of the analytical Standard Operating Procedures (SOPs). Some participants expressed the opinion that it should be left to an assessor’s discretion as to how much they review on-site and how much they review off-site. It was noted that this raises an issue of reciprocity if assessors from some states are checking all SOPs while assessors from other states are checking only a statistical sample of the laboratory’s SOPs. It was suggested that the issue must be resolved before the pilot assessor training course is presented. The issue was deemed a fundamental issue and one that should be discussed at the next interim meeting in order to get input from NELAC stakeholders. In response to the comment that the Accrediting Authorities are addressing this issue in order to establish reciprocity, it was suggested that the NELAC On-site Assessment Committee coordinate more formally with the group of Accrediting Authorities.

Unit 16 (“NELAC On-Site Assessment”) - In response to the suggestion that a written audit agenda be included in this training unit, Ms. Rosanna Buhl agreed to provide Dr. Hunt with a sample agenda. The committee noted that it is not necessary that every question on the assessment checklist be asked because an answer to a question is not objective evidence of noncompliance. It was suggested that every question must be “reviewed” rather than “asked.” The committee engaged in considerable discussion of whether assessors should communicate their findings to laboratory personnel during the inspection. Some participants advocated asking

specific questions about any apparent noncompliance in order to be assured that there is no misinterpretation. Others noted that laboratory personnel are blind-sided if they are not informed of the assessor's findings during the debriefing. It was noted that the goal in an International Standards Organization (ISO)-type audit is to avoid any disagreement, to always present whatever appears to be noncompliance in order to avoid misunderstandings with laboratory personnel. It was also suggested that the course materials include examples of valid technical disagreements.

Unit 17 (“NELAC Post-Assessment”) - The committee noted that assessors must know how rapidly they need to complete their reports so that they reach the Accrediting Authority by the time specified in the NELAC Standards. A problem arises in stipulating “how” to mail or ship reports, however, because the Standards do not specifically address that issue. The committee also noted that the assessor is not auditing SOPs. The assessor is auditing the laboratory *against* its SOP's and must assess the adequacy of SOPs. The NELAC Quality Systems Standard contains 23 specific elements that must be covered in the SOP (Section 5.10.1). It was suggested that the training materials use the wording from the Standard rather than refer to “adequacy.” The committee then entered into considerable discussion of “adequacy” as referenced in the NELAC On-Site Assessment Standard (Section 3.6.1.g). It was suggested that adequacy of SOPs may be defined by three elements: 1) that the laboratory has SOPs for all work performed in that laboratory, 2) that the SOPs are complete enough as to be repeatable, and 3) that the SOPs are consistent with the reference method. It was suggested that the committee discuss clarifying the language in NELAC Standard Section 3.6.1.g at the next interim meeting in order to get input from NELAC stakeholders.

A general suggestion was made that the committee consider expanding the training course and get input from stakeholders at the interim meeting regarding the level of detail needed. This met with committee approval. In closing, committee members agreed to review all units along with Dr. Hunt's comments and submit their comments electronically to Dr. Hunt by Monday, November 29, 1999. They reminded Dr. Hunt to make sure that earlier units are consistent in their use of the words “assessor” and “assessment.”

CONCLUSION

The next On-site Assessment Committee teleconference is scheduled for Tuesday, December 7, 1999, from 12:30 p.m. to 2:30 p.m. EST. Ms. Marlene Moore and Ms. Buhl indicated that they would not be able to attend.. The allotted teleconference time coming to an end, the committee meeting was adjourned at 12:30 p.m. EST.

ACTION ITEMS
ON-SITE ASSESSMENT COMMITTEE TELECONFERENCE
NOVEMBER 22, 1999

Item No.	Action	Date to be Completed
1.	Committee members will submit final comments on draft training materials, including inconsistencies between training materials and NELAC Standards, electronically to Dr. Hunt.	11/29/99
2.	Dr. Hunt will ensure that earlier training units are consistent in the use of the words “assessor” and “assessment.”	11/29/99
3.	Committee will include the following issues in discussion at the Fifth Interim NELAC Meeting: a) Clarification of whether AARB monitors EPA or NELAP b) Clarification of CBI issues, including whether third party assessors may sign CBI papers on behalf of the Accrediting Authority and whether non-government employees are held to the same accountability standards as government employees c) Issue of reciprocity arising from question of whether an assessor must review all laboratory SOPs or a statistical sample of the SOPs d) Issue of “adequacy” of SOPs, including committee’s suggested three-item clarification language (see minutes) e) Issue of expanding the Basic NELAC Assessor Training Course, including soliciting input from NELAC stakeholders as to level of detail needed in the course f) Review of NELAC On-site Assessment and Quality Systems Standards to be sure that they are consistent	NELAC Vi
4.	Committee will coordinate more formally with the NELAC Quality Systems Committee on issues that bridge the two committees.	To Be Decided
5.	Committee will coordinate more formally with Accrediting Authorities to resolve issues of reciprocity.	To Be Decided
6.	Ms. Buhl will provide Dr. Hunt with a sample audit agenda for inclusion in training materials.	12/07/99

PARTICIPANTS
ON-SITE ASSESSMENT COMMITTEE TELECONFERENCE
NOVEMBER 22, 1999

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